



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cosponsorship with the American College of Gastroenterology, the American Gastroenterological Association, the Crohn's and Colitis Foundation of America, Inc., the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition, and the Pediatric IBD Foundation, is announcing a 2-day public workshop entitled "Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics (GREAT II)." Partners and stakeholders planning the workshop also include patients and representatives from the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health. The purpose of this workshop is to provide a forum to consider issues related to endpoints that can support drug development in the following disease areas: Pediatric and adult inflammatory bowel diseases.

DATES: The public workshop will be held on October 21 and 22, 2013, from 8:30 a.m. to 5 p.m.

ADDRESSES: The public workshop will be held at the National Institutes of Health, 31 Center Dr., Natcher Conference Center, Building 45, Bethesda, MD 20892-2178.

FOR FURTHER INFORMATION CONTACT: Kevin Bugin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-2302, FAX: 301-796-9905, email: Kevin.Bugin@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

This workshop will address endpoints for registration trials. Stakeholders, including industry sponsors, academia, patients, and FDA, will be engaged to address challenging issues related to selection of endpoints and assessment methodologies in registration trials for products intended to treat adult and/or pediatric inflammatory bowel disease. The definition and measurement of treatment benefit in Crohn's disease registration trials, the role of existing and future clinical outcome assessments including development of patient reported outcome measures, timing of endpoint assessments, and dose-finding strategies will be discussed. In addition, there will be a followup to previous workshop discussions of endpoints and clinical trial design for ulcerative colitis registration trials. Strategies and methods to overcome the challenges of developing drugs in pediatric populations and facilitate the collection of dosing, safety, and efficacy information for drugs not currently approved for use in children will be discussed.

Participation in the Public Workshop:

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at <http://www.great2.org> before October 1, 2013. For those without Internet access, please contact Kevin Bugin (see FOR FURTHER INFORMATION CONTACT) to register. Onsite registration will not be available.

If you need special accommodations due to a disability, please contact Kevin Bugin (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Transcripts: Transcripts of the workshop will be available for review at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and on the Internet at <http://www.regulations.gov> approximately 30 days after the workshop. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: August 8, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013-19684 Filed 08/13/2013 at 8:45 am; Publication Date: 08/14/2013]